No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit

BRIEF OF DR. DENTON COOLEY AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICUS CURIAE

Dr. Denton Cooley submits this brief amicus curiae in support of respondent MEDTRONIC, INC. on the writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered March 29, 1989.

Dr. Denton Cooley, M.D. is an internationally renowned cardiac surgeon. He is also the Surgeon in Chief of the Texas Heart Institute, one of the world's leading cardiac research centers, located in Houston.

Dr. Cooley, together with his colleagues at the Texas Heart Institute, is actively involved in research into the causes and treatment of cardiac disease. This research includes carrying out clinical trials of new drugs and medical devices developed by pharmaceutical companies and medical device manufacturers.

Dr. Cooley also has an extensive practice treating patients, many of whom have advanced or complicated conditions which are not readily treatable by conventional means. It is very important to him to be able to offer all his patients the best available treatment for their particular condition.

In addition, Dr. Cooley's position at the Institute involves him in raising funds for the research activities. As federal spending has been cut back in recent years, the money for research has increasingly had to come from industry.

All these activities would be adversely affected if the very narrow view of the scope of 35 U.S.C. § 271(e)(1) put forward by petitioner Lilly and its supporting amici were to prevail. Clinical trials of new devices would be fraught with the danger of patent infringement litigation, and even animal and bench testing would be affected by this chilling threat. A likely result is that much clinical research involving medical devices will be driven out of the United States to foreign research institutes in countries where the law is not so restrictive, closely followed by the best physicians and surgeons and the corporate research

support. The Texas Heart Institute could not maintain its present world leadership role in cardiac research and treatment under those circumstances.

SUMMARY OF ARGUMENT

Congress cannot have intended the 1984 provisions allowing testing for regulatory purposes prior to the expiry of a dominant patent to exclude medical devices, because the effects of excluding medical devices are clearly contrary to the public interest.

The inability to perform clinical testing until the dominant patent has expired, which could be longer than the basic seventeen years if an extension is obtained, could seriously delay the introduction of improved technology. It may even result in some improvements not being made at all. This could have a serious effect on the standards of patient care in this country.

If the testing were to be done abroad, as Lilly wants, the final result will be that the United States will lose some of its most innovative doctors, medical scientists and engineers, and much-needed corporate funding, to foreign institutions. Such a loss of talent and funds can only damage this country's standing as a leader in the development of medical technology.

ARGUMENT

Petitioner Lilly is contending for an interpretation of 35 U.S.C. § 271(e)(1) which would outlaw all U.S. clinical testing of new medical devices which come within the claims of an existing patent for the whole term of the patent, including any extension. This interpretation, combined with the present law which does not exempt from

infringement experimental use where there is an ultimate commercial motive, however remote, behind the experiments, would have a disastrous effect on research into and treatment of cardiac disease in the United States. This would be contrary to the constitutional intent behind the patent system of promoting the progress of science and technology, and thus is not likely to have been the intent of Congress in enacting section 271(e)(1).

I.

Clinical Trials Of Medical Devices Are Vitally Important In The Treatment Of Heart Disease

It is the literal truth to call medical devices such as implantable defibrillators "life-saving". There are many patients who today are leading healthy, enjoyable lives, who just a few years ago would have been unable to live a normal life, or who may even have died. This is thanks to the remarkable advances in medical device technology that have occurred in recent years.

These rapid advances in medical technology will continue, given the right climate for research and testing. This will require sufficient funding, innovative engineers and doctors, the ability to do bench and animal testing of prototype devices, and the ability to do scientific clinical trials on human subjects. Up until now, all of these ingredients have been present in the United States, making this a leading country in medical device development.

A total inability to perform clinical trials until the expiry of the seventeen year patent term (or even longer, if Lilly's claim to benefit from the patent term extension without the *quid pro quo* of pre-expiry regulatory testing

were to succeed) would seriously damage the whole program. Most cardiac medical devices become obsolete in a much shorter time than seventeen years, being replaced by improved, more sophisticated and reliable devices. Some of these improved devices can treat conditions that were previously untreatable, or can treat other conditions more effectively. If the lengthy testing needed to satisfy FDA requirements for new medical devices cannot begin in the United States until the expiry of the seventeen or more years of the patent term, at least some new devices may never be made.

II.

Lack Of Improvements Will Adversely Affect Patient Care

Doctors want to provide their patients with the best treatment available to deal with that person's particular condition. While a particular patented device will likely be of benefit to certain patients, it is unlikely to meet every need. An improvement to the patented device may be desirable to treat some conditions, but the patentee is not always ready or willing to make that improvement in the absence of competition. Some patients may be benefitted by being subjects in a clinical trial of an improved device, and it is to the advantage of the medical profession and their patients to have the improved device approved by the FDA as soon as possible.

On the other hand, where a tried and approved device meets the patient's needs, that device would normally be prescribed, not the experimental improvement. Lilly and certain of its supporting amici argue that there would be an enormous loss of sales as the result of clinical testing.

However, this ignores the fact that the majority of doctors, a body many times larger than the very limited number of doctors participating in the clinical trials, will be unable to prescribe the experimental device. Even those doctors in the trial are unlikely to select patients for the trial who can be treated perfectly well with the approved device. The loss of sales to the patentee as a result of clinical trials has been greatly exaggerated.

III.

Clinical Research In The United States Will Be Harmed

Lilly has several times suggested that there is no justification for allowing regulatory testing of medical devices prior to the expiration of the patent term, because such testing could equally well be done abroad. *See, e.g.*, Brief for the Petitioner, filed November 21, 1989, page 31 n.21, and Lilly's Application To Stay Mandate Of The Federal Circuit, filed in this Court, July 21, 1989, pages 21, 24-25. That is likely to have much more devastating effects on American medical research and device technology than allowing the regulatory testing of new devices prior to the expiration of a patent.

First, leading clinical researchers would want to go to where the testing is carried out. The innovators and leaders amongst medical practitioners would also want to be where they could participate in clinical trials and offer their patients the latest in medical technology. In fields like cardiology, patients will often travel across the world in order to receive treatment from well-known doctors at leading centers, such as the Texas Heart Institute. Of course, those Americans who could not afford to travel abroad would not be able to benefit from these advances being tested overseas.

It is possible that this loss of clinical research facilities would tend to draw the more basic research abroad as well. Certainly, corporations would be more likely to put research funds into organizations which could carry out clinical testing of new medical devices, so U.S. institutions could see a diminution in the funds available from industry for medical device research.

There is no doubt that even a partial shift to overseas institutions of research, of highly qualified doctors and researchers, and of research funding would seriously damage the United States' claim to be a leader in medical technology, as well as damaging the medical institutions in this country at which the research is carried on. It is unbelievable that this could have been the intention of Congress.

Respectfully submitted,

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In considering the Drug Price Competition and Patent Term Restoration Act of 1984, Congress made it clear that except for the limited patent term extension for which it was providing, there was to "be no other direct or indirect method of extending patent term." H.R. Rep. 98-857, 98th Cong., 2d Sess., pt. I, at 15 (1984). There is no dispute about that. The idea was to make the patent owner "whole", to give him back as much of his original 17-year commercial term as possible. No one ever contemplated giving him a *bonus*.

What does Lilly say about an original 17-year patent monopoly being transformed into an effective 19-year monopoly? Lilly has taken the position that the illustrated *de facto* extension of the original term can be avoided because the competitor may begin testing *outside the United States* during the 2-year patent term extension. (Lilly Brief, p. 31 n. 21). (Presumably, foreign testing could begin even earlier.) Lilly says that under 21 C.F.R. Section 814.15, the FDA can approve a medical device based solely on foreign testing. The real question, however, is whether Congress could possibly have intended, when drafting a Statute designed to balance competitive domestic interests, that all American medical device manufacturers (except the patent owner) should ship their manufacturing and clinical affairs departments overseas so that American pacemakers, insulin pumps, hearing prostheses, etc. could be tested only on non-Americans. According to Lilly, the answer has to be in the affirmative.

Lilly must also be proceeding on the assumption that the rest of the world lacks effective patent enforcement procedures which might otherwise block the conduct of a clinical trial in a foreign country in which Lilly has also secured patent protection.

Any interpretation of Section 271(e)(1) must take into account the possible extension of a patent under jointly-enacted Section 156. Lilly obtained the benefit of just such an extension; only by construing Section 271(e)(1) as applying to medical devices will impermissible *de facto* extensions be avoided.

CONCLUSION

For the foregoing reasons, Telectronics respectfully submits that this Court should affirm the Federal Circuit's decision.

Respectfully submitted,

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